

The Claims:

1. A process for providing a uniform drug rate of release from a dosage form, wherein the dosage form comprises a composition, a dose of drug in the composition, and a hydrophilic polymer in the composition; and wherein the process comprises (1) formulating the composition with a drug possessing a size less than 150 μm , and (2) formulating the composition with a hydrophilic polymer of less than 250 μm size; whereby, through the copresence of (1) and (2) in the composition, the drug is delivered at the uniform rate of release from the dosage form.

2. The process for providing the uniform drug rate of release from the dosage form according to claim 1, wherein the composition is enveloped by a wall comprising means for releasing the drug from the dosage form.

3. The process for providing the uniform drug rate of release from the dosage form according to claim 1, wherein the composition is surrounded by an outer wall and an inner subcoat, with means in the dosage form for releasing the drug from the dosage form.

4. A process for providing a uniform drug rate of release from a dosage form, wherein the dosage form comprises: a drug layer comprising a dose of drug and a hydrophilic polymer, and a dispensing layer comprising means for dispensing the drug layer from the dosage form; and wherein the process comprises formulating the drug layer with a drug possessing a particle size up to 150 μm and with a hydrophilic polymer possessing a particle size up to 250 μm , which, through the cooperation of the drug particles and the hydrophilic polymer particles, and the dispensing layer assisting the drug layer, the drug is delivered at a substantially uniform rate of release from the dosage form.

5. The process for promoting the uniform drug rate of release according to claim 4, wherein the hydrophilic polymer particle cooperates with the

drug particle as a pharmaceutical carrier for delivering the drug from the dosage form.

6. The process for providing the uniform drug rate of release according to claim 4, wherein the dispensing layer assists in displacing the drug layer from the dosage form.

7. The process for providing the uniform drug rate of release according to claim 4, wherein a wall encases both the drug layer and the dispensing layer, and comprises means for releasing the drug from the dosage form.

8. The process for providing the uniform drug rate of release according to claim 4, wherein a wall surrounds the drug layer and the dispensing layer, a subcoat is between the wall, the drug layer and the dispensing layer, and the dosage form comprises exit means for releasing the drug from the dosage form.

9. A dosage form for the delivery of a drug, wherein the dosage form comprises:

- (a) a composition;
- (b) a dose of drug of less than 150 μm in the composition;
- (c) a hydrophilic polymer of less than 250 μm in the composition;
- (d) a wall comprising a composition permeable to the passage of fluid that surrounds the dose of drugs and the hydrophilic polymer; and
- (e) means in the wall for delivering the drug at a substantially uniform rate from the dosage form.

10. A dosage form for the delivery of a drug, wherein the dosage form comprises

- (a) a drug composition;
- (b) a dose of drug of less than 150 μm in the drug composition;

- (c) a hydrophilic polymer of less than 250 μm in the drug composition;
- (d) a coat that surrounds the drug composition comprising means for delaying release of drug from the drug composition;
- (e) a wall comprising a composition that surrounds the coat; and,
- (f) means in the dosage form for delivering the drug from the dosage form over time.

11. The dosage form according to claim 10, wherein the drug is a member selected from the group consisting of verapamil, nifedipine, nilvadipine, flunarizine, nimodipine, diltiazem, nicardipine, nitrendipine, nisoldipine, felodipine, amlodipine, isradipine, cinnarizine and fendiline.

12. The dosage form according to claim 10, wherein the drug is a member selected from the group consisting of ramipril, fusinopril, altiopril, benazepril, libenzapril, alacepril, cilazapril, cilazaprilat, perindopril, zofenopril, enalapril, lisinopril, imidapril, spirapril, rentiapril, captopril, delapril, olindapril, indolapril and quinapril.

13. A dosage form for the delivery of a drug, wherein the dosage form comprises:

- (a) a drug composition comprising a drug less than 150 μm size and a pharmaceutically acceptable hydrophilic polymer carrier less than 250 μm size;
- (b) a displacement composition in contact with the drug composition comprising means for causing fluid to enter the displacement composition, whereby the displacement composition increases in volume and displaces the drug composition from the dosage form;
- (c) a wall, comprising means for permitting a fluid to enter the dosage form, that surrounds the drug composition and the displacement composition; and
- (d) means in the wall for delivering the drug as a substantially uniform rate over a dispensing time.

14. The dosage form for delivering the drug according to claim 13, wherein the drug is a member selected from the group consisting of a calcium channel blocker and an angiotensin enzyme inhibitor.

15. The dosage form for delivering the drug form for delivering the drug according to claim 13, wherein this drug is a member selected from the group consisting of alpha receptor blocking drugs, beta receptor blocking drugs, antianginal drugs, antiarrhythmias drugs, antiembolus drugs, antihypertensive drugs, digitalis drugs, hemorheologic drugs, inotropic drugs, myocardial infarction prophylaxis drugs, cerebral vasodilators, coronary vasodilators, peripheral vasodilators and vasopressor drugs.

16. A dosage form for delivering a drug orally to a patient in need of a drug, wherein the dosage form comprises:

(a) a drug composition comprising a drug having a particle size up to and including 150 μm , and a hydrophilic polymer carrier for the drug having a particle size up to and including 250 μm ;

(b) a displacement composition in contrast with the drug composition comprising a polymer that expands in the presence of fluid for displacement of the drug composition from the dosage form;

(c) a coat, free of drug, which surrounds the drug and the displacement composition for slowing the passageway of fluid into the dosage form;

(d) a wall that surrounds the coat and is permeable to the passage of fluid; and,

(e) means in the dosage form for delivering the drug from the dosage form at a substantially uniform rate over time.

17. The dosage form for delivering the drug according to claim 16, wherein the drug composition comprises an antioxidant.

18. The dosage form for delivering the drug according to claim 16, wherein the drug composition comprises a surfactant.

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19. The dosage form for delivering the drug according to claim 16, wherein the drug is a member selected from the group consisting of verapamil, isradipine, nifedipine, nilvadipine, flunarizine, nimodipine, diltiazem, nifedipine, nitrendipine, nisoldipine, felodipine, amlodipine, cinnarizine, fendiline, prazosin, clonidine, pinacidil and alfuzosin.

20. The dosage form for delivering the drug according to claim 16, wherein the drug is a member selected from the group consisting of quinapril, indolapril, olindapril, delapril, captopril, rentrapril, spirapril, imidapril, lisinopril, enalapril, enalaprilat, zofenopril, perindopril, cilazaprilat, alacepril, libenzapril, benazepril, altopril, fosinopril and ramipril.

21. A method for the management of blood pressure in a patient, wherein the method comprises:

(a) admitting orally into the patient a therapeutic composition comprising a dose of drug indicated for the management of blood pressure with the drug possessing a particle size of less than 150 μm , and a pharmaceutically acceptable hydrophilic carrier for the drug possessing a particle size of less than 250 μm ; and,

(b) managing the blood pressure by codelivering the drug and the accompanying polymer at a substantially uniform rate of release from the composition to provide an effective dose for managing the blood pressure of the patient.

22. The method for the management of blood pressure according to claim 21, wherein a wall with means for providing a passage therethrough surrounds the therapeutic composition.

23. The method for the management of blood pressure according to claim 21, wherein a coat comprising a hydroxyalkylcellulose surrounds the therapeutic composition and a wall comprising a member selected from cellulose

ester, cellulose ether and cellulose ester-ether surrounds the coat, with means in the coat and in the wall for delivering the drug and polymer from the composition.

24. The method for the management of blood pressure according to claim 21, wherein the drug is a member selected from the group consisting of alpha-receptor, beta-receptor, antihypertensive, alpha-blocker, beta-blocker, calcium channel blocker, angiotensin enzyme inhibitor, vasodilator, cerebral, coronary, peripheral, and alpha adrenergic drugs.

25. A method for the management of the systemic physiology of a patient, wherein the method comprises:

(a) admitting orally into the patient a therapeutic composition comprising a dose of drug indicated for the management of a systemic physiology with the drug possessing an average particle size of less than 150 μm , and a therapeutically acceptable hydrophilic polymer possessing an average particle size of less than 250 μm for delivering the drug from the therapeutic composition; and a delivery composition in contact with the therapeutic composition comprising a therapeutically acceptable hydrophilic polymer possessing a greater number-average molecular weight than the hydrophilic polymer present in the therapeutic composition for aiding in delivering the drug from the therapeutic composition; and,

(b) managing the systemic physiology of the patient by the codelivery of the drug and the polymer at a substantially uniform rate of release from the therapeutic composition aided by the delivery composition to provide an effective dose for the management of the systemic physiology of the patient.

26. The method for the management of the systemic physiology of a patient according to claim 25, wherein a wall with means for providing a passage therethrough surrounds the therapeutic composition and the delivery composition.

27. The method for the management of the systemic physiology of a patient according to claim 25, wherein an inner coat surrounds both the therapeutic composition and the delivery composition, and an outer wall surrounds the inner coat, with means in the coat and wall for delivery of the drug from the therapeutic composition.

28. The method for the management of the systemic physiology of the patient according to claim 25, wherein the management of the systemic physiology comprises administering a drug comprising vasodilating, hypotensive and antianginal therapy.

29. The method for the management of the systemic physiology of the patient according to claim 25, wherein the management of the systemic physiology comprises administering a drug for alleviating angiotensin related hypertension in the patient.

30. A method of timetherapy for delivering a drug to a patient at a selected time, wherein the method comprises administering orally to the patient a therapeutic composition comprising a dose of drug possessing an average particle size up to 150 μm and a pharmaceutically acceptable polymer possessing an average particle size up to 250 μm , and means for governing the release of drug from the therapeutic composition, whereby the drug is released by the means in a substantially uniform rate of release at the selected time for timetherapy.

31. The method of timetherapy according to claim 30, wherein the drug is delivered at a time needed by the patient.

32. A method of timetherapy for delivering a drug to a patient over a selected time for the management of hypertension, wherein the method comprises orally administering to the patient a therapeutic composition comprising a calcium channel blocker drug and an angiotensin converting

enzyme inhibitor drug possessing an average particle size up to 150 μm and a pharmaceutically acceptable polymer possessing an average particle size up to 250 μm , and means for governing the release of the drugs from the therapeutic composition, whereby the drugs are timed-release in a substantially uniform dose over the selected time for the timetherapy management of hypertension.

³³₃₈. A dosage form comprising verapamil hydrochloride adapted to release said verapamil hydrochloride at a rate having a percentage deviation of not more than 5% from the mean release rate over a prolonged period of time.

³⁴₃₉. The dosage form of claim ³³₃₈ wherein the prolonged period of time is four hours or more.

³⁵₄₀. The dosage form of claim ³⁴₃₉ wherein the amount of verapamil hydrochloride in the dosage form is 25 ng to 750 mg.

³⁶₄₁. The dosage form of claim ³⁴₃₉ wherein the amount of verapamil hydrochloride in the dosage form is 240 mg.

³⁷₄₂. The dosage form of claim ³³₃₈ wherein release is initiated about four hours after contact with an aqueous environment.

³⁸₄₃. A dosage form for the delivery of a drug, wherein the dosage form comprises:

- (a) a drug composition;
- (b) a dose of drug comprising a size of less than 150 μm in the drug composition;
- (c) a hydrophilic polymer comprising a size of less than 250 μm in the drug composition;
- (d) a coat that surrounds the drug composition comprising means for delaying release of drug from the drug composition;
- (e) a wall comprising a composition that surrounds the coat; and

- (f) means in the dosage form for delivering the drug from the dosage form; wherein said drug is verapamil hydrochloride; and wherein the dosage form releases said verapamil hydrochloride at a rate having a percentage deviation of not more than 5% from the mean release rate over a prolonged period of time.

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